Eur J Vasc Endovasc Surg **35**, 514–521 (2008)
doi:10.1016/j.ejvs.2007.12.002, available online at http://www.sciencedirect.com on ScienceDirect

Contrast Enhanced Magnetic Resonance Angiography Versus Intra-arterial Digital Subtraction Angiography for Treatment Planning in Patients with Peripheral Arterial Disease: A Randomised Controlled Diagnostic Trial

A.C. Vahl,[1*] J. Geselschap,[2] A.D. Montauban van Swijndregt,[2] J. Smit,[2] J. Sala,[1] K. Turkcan,[1] L.M Dijksman[3] and M.J.T. Visser[1]

Departments of [1]Vascular Surgery, [2]Radiology, and [3]Teaching Hospital, Onze Lieve Vrouwe Gasthuis, Amsterdam, The Netherlands

Objectives. *To compare the diagnostic and therapeutic confidence, patient outcome and costs between MRA and DSA as the initial diagnostic imaging test, in patients with symptomatic arterial disease of the leg.*
Design. *Randomised controlled diagnostic trial.*
Materials and methods. *Patients were randomly allocated to MRA (*n = *97) or DSA (*n = *100). Primary outcomes were: ability to make treatment plan and patients satisfaction. Secondary endpoints were: type of treatment and costs.*
Results. *A treatment plan was determined for each included patient. Additional imaging was necessary in 11% of patients in the MRA group compared to 10% in the DSA group (*p = *0.5). 84% of the patients who received MRA judged the diagnostic work up as comfortable compared to 57% who had DSA (*p = *0.013). Within 4 months of randomization 30 patients in the MRA group compared to 34 patients in de DSA group underwent operative procedures; 39 versus 36 patients respectively underwent angioplasty. The mean total in-hospital costs during the first 4 months were €4768,- in the MRA group compared to €4697,- in the DSA group (95% CI of difference −1331;1472).*
Conclusions. *In patients with peripheral arterial disease of the leg an adequate treatment plan can be made with MRA. This diagnostic strategy was experienced as more comfortable and less painful compared to DSA. Total diagnostic and treatment costs of both strategies were comparable.*

Keywords: Magnetic resonance angiography; Digital subtraction angiography; Peripheral vascular diseases; Treatment costs; Patient satisfaction.

Introduction

For invasive treatment planning in patients with peripheral arterial disease, visualisation of the vascular tree is necessary. The reference standard is digital subtraction angiography (DSA). As first line investigation duplex scanning (DUS) can be performed. However, DUS is time consuming and investigator dependent. The drawbacks of DSA are a compulsory admission, as well as risk of complications like contrast allergy or renal toxicity. CTA or MRA are less invasive alternatives and both have been evaluated in diagnostic research. Contrast enhanced MRA (CE MRA) has been proven a reliable technique with an adequate diagnostic performance to replace DSA, described in individual studies as well in meta-analysis.[1–6] Drawbacks of MRA are less optimal imaging of distal arteries[7,8]or overestimation of stenoses.[9] One group was able to detect more patent distal arteries.[10] To avoid venous over projection of the crural vessels in order to visualize more patent arteries, the scanning protocol had been changed performing the imaging from distal to proximal.[11]

MRA proved to be a reliable method for making a treatment plan.[12,13] However, in published series as well as in our own experience, 7 to 10% of the patients need additional diagnostic work up after MRA.[12] All previous studies have to be classified as diagnostic research: both MRA and DSA were evaluated on the same patient, and compared with

*Corresponding author. Dr. A. C. Vahl, MD, PhD, MSc, Dept. of Surgery, P.O. Box 95500, 1090 HM Amsterdam, The Netherlands.
E-mail address: a.c.vahl@olvg.nl

1078–5884/000514 + 08 $34.00/0

the treatment plan. There is no literature about evaluation of clinical utility and patient outcomes observed when performing MRA instead of DSA in daily practice.

The purpose of our study was to prospectively compare the diagnostic and therapeutic confidence, the patient outcome (in terms of treatment) and costs between MRA and DSA as the initial diagnostic imaging test in patients with symptomatic arterial disease of the leg. We performed a diagnostic trial where the imaging was part of the treatment.

Material and Methods

Patients

Between November 2004 and November 2006, we approached all eligible patients from the department of vascular surgery. Baseline characteristics were collected for each patient with symptomatic arterial disease (ankle-brachial index of less than 0.90) and were referred for a diagnostic imaging work-up to evaluate the feasibility of a revascularisation procedure. Patients had either severe disabling intermittent claudication (Fontaine classification IIb) or critical ischemia according to the SVS/ISCVS criteria (Fontaine classification III or IV).[14]

Excluded were patients with acute ischemia and contra-indications for MRA or DSA: Kreatinine >170 μmol/l, claustrophobia, metal clips in vital organs and pacemakers.

Primary endpoints were patient satisfaction and necessity for additional imaging. Secondary endpoints were treatment plan, types of treatment (conservative, angioplasty, surgery) and costs.

The study was approved by the hospital institutional review board (WO 03.070) and informed consent was obtained from all patients. The study was performed according to Good Clinical Practice guidelines.[15] Data are analyzed and reported in accordance with the guidelines of the Consolidated Standards of Reporting Trials.[16]

Study design

Patients were randomly allocated to either MRA as diagnostic strategy, or DSA. A non-stratified computer-generated randomization sequence was made. The allocation sequence was concealed by means of sealed opaque consecutively numbered envelopes. Patients were enrolled by the vascular surgeons, who were unaware of the randomization sequence.

Imaging techniques

Imaging was performed on a 1.5 Tesla MR system (Philips Gyroscan Intera T15-N release 8.1.1; Philips Medical Systems, Best, the Netherlands). Patients were placed in the supine position and entered into the magnet with their feet first. The lower legs were immobilized and placed into the surface coil.

Axial TOF views were used to plan the subsequent image volumes for the ce-MRA scan at the three stations: aortoiliacal, femoral and crural station (TR (ms)/TE (ms) 6.9/11.6, flip angle 50 degrees, field of view (FOV) $430 \times 100\ mm^2$, matrix $256 \times 256\ mm^2$). The Acquisition of the contrast enhanced images were performed with a fast 3D spoiled gradient-echo sequence (T1-FFE/M; TR = 6.0; TE = 1.52; flip angle = 35, FOV = 430 mm, no flow compensation). The standard quadrature body coil was used for signal transmission and reception. Non-enhanced 3D data sets were obtained for each station and later subtracted from the identical contrast-enhanced data sets to increase vessel to background noise.

Images were acquired in the coronal plane and the number of slices and imaging parameters were for all the 3 stacks identical: 70 slices of 1.5 mm. The actually measured partition thickness was 3 mm and later interpolated to 1.5 mm. In-plane resolution was $0.84 \times 0{,}84 \times 1.5\ mm^3$. The maximum total coverage in the feet head direction was 126 cm. To ensure that all arteries were included in the FOV, we used a 30-mm overlap between consecutive stations. The scan time of the individual stacks was 28.3 sec. Table movement was scanner controlled and the time between 2 consecutive scans was approximately 5 seconds. For all patients a dedicated peripheral surface coil was used at the crural station (Synergy Body Coil, 4 elements, Philips medical system).

A paramagnetic contrast agent (0.4 ml Gd/kg bodyweight, Gadodiamine 0.5 M [Omniscan®, Nycomed]) was injected per patient to enhance intravascular signal. The body-weight-adjusted dose was diluted with 0.9% saline to a total standard scan volume of 33 ml contrast medium solution. Those patients of over 82.5 kg in whom the total amount of the body-weight-adjusted dose exceeded 33 ml of contrast agent were also maximized to the standard scan volume of 33 ml. Contrast medium was administered as a single continuous bolus in an antecubital vein at a rate of 1.0 ml/sec for the first 10 ml, followed by a rate of 0.2 ml/sec for the next 20 ml of contrast. Immediately after injection of contrast material, 20 ml of normal saline was administered at a flow rate of 0.2 ml/sec to flush tubing and veins. All injections